DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 11, 2015

Cardiac Insight, Inc.
% Deborah Sheffield
Regulatory Consultant
Deborah L. Sheffield Consulting
5672 Flagler Road
Norland, Washington 98358

Re: K142468
Trade/Device Name: Stealth™ Monitor
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MLO, DXH, DPS, DSH
Dated: August 31, 2014
Received: September 3, 2014

Dear Deborah Sheffield,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) PREMARKET NOTIFICATION
INDICATION FOR USE

510(k) Number: k142468

Device Name: Stealth™ Monitor

Indications For Use:

The Stealth™ Monitor is a prescription only single use, continuous recording ECG monitor that can be worn up to 168 hours (7 days) during activities of daily living. It is indicated for use on adult patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, dizziness, anxiety, fatigue, syncope, pre-syncope, light-headedness, shortness of breath and where a software-assisted analysis of the potential causes of these symptoms is desirable.

Prescription Use X **AND/OR** **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **(21CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Premarket Notification

Summary

1. Submitter's Information

Company Name:	Cardiac Insight, Inc.
Company Address:	2815 Eastlake Avenue, Suite 300 Seattle, WA 98102
Company Phone:	206-596-2060
Contact:	Brad Harlow / bharlow@cardiacinsightinc.com

Trade Name:	Stealth System
Common Name:	ECG Recorder
Classification Name:	Electrocardiograph, Ambulatory, With Analysis Algorithm 21 CFR 870.2800

2. Predicate Device Identification

Device Name	Clearance Number	Product Code
SEER MC	K042782	MLO
AliveCor Heart Monitor	K142743	DXH, DPS
Stealth™ System (M100)	K130288	DSH

All predicates are Class II devices.

3. Indications for Use and Device Description

Indications for Use

The Stealth™ Monitor is a prescription only single use, continuous recording ECG monitor that can be worn up to 168 hours (7 days) during activities of daily living. It is indicated for use on adult patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, dizziness, anxiety, fatigue, syncope, pre-syncope, light-headedness, shortness of breath and where a software-assisted analysis of the potential causes of these symptoms is desirable.

The Indications for Use are consistent with those of the predicate devices.

Device Description

The Stealth™ Monitor is a small, lightweight, patch-style, single-use cardiac monitor designed for ambulatory collection of electrocardiographic (ECG) data continuously for up to 168 hours (7 days) and ECG signal characterization. It is worn on the patient's chest similar to an adhesive bandage. The housing is constructed of a foam material making the device very lightweight (less than 9 grams).

A software application is installed at a physician's office to receive the data from the monitor using a direct connection. Data retrieved from the monitor may be printed or saved and stored for later viewing. The DSD software has the ability to generate reports as well as the ability to save a full disclosure ECG file for viewing.

4. Technological Characteristics of the Device as Compared to Predicate Devices

Device Characteristics	Stealth™ System S200 (K142468)	SEER MC (K042782)	AliveCor Heart Monitor (K142743)	Stealth™ System S100 (K130288)
Indications for Use	The Stealth™ Monitor is a prescription only single use, continuous recording ECG monitor that can be worn up to 168 hours (7 days) during activities of daily living. It is indicated for use on adult patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, dizziness, anxiety, fatigue, syncope, pre-syncope, light-headedness, shortness of breath and where a software-assisted analysis of the potential causes of these symptoms is desirable.	The SEER MC Ambulatory Digital Analysis Recorder is intended to provide ambulatory ECG signal and automated analysis of the recorded ECG data. Results of the automated analysis, when used in conjunction with an ECG review system, are intended to assist the physician in the interpretation of the recorded data.	The AliveCor Heart Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The AliveCor Heart Monitor also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The AliveCor Heart Monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals.	The Stealth™ Monitor is a prescription only single use, continuous recording ECG monitor that can be worn up to 24 hours. It is indicated for use with patients where it would be desirable to record ECG signals for this period of time.
Product Code	MLO	MLO	DXH, DPS	DSH
Device Classification	II / 870.2800	II / 870.2800	II / 870.2920	II / 870.2800
Where used	Ambulatory outpatient use	Ambulatory outpatient use	Ambulatory outpatient use	Ambulatory outpatient use
Prescription Req'd	Prescription only	Prescription only	Prescription only	Prescription only
Adult/Pediatric	Adult	Both	Adult	Adult

Single Use/ Reusable	Single use	Reusable, single-use electrodes	Reusable	Single use
ECG Storage	At least 168 hours	48 hours	"Practically unlimited"	At least 24 hours
Recording Type	Continuous	Continuous	Continuous	Continuous
Application/Wear	Adhesive, body worn	Holster for device, adhesive electrodes	Patient applied, held in place for duration of recording	Adhesive, body worn
User Interface	On/Off, Event button	On/Off, Event Button	Smartphone app	On, Event Button
Data Transfer	USB 2.0	Serial	Telephonic/Network	RS-232 to USB 2.0
Arrhythmias and/or statistics	Normal, fastest heart rate, slowest heart rate, average heart rate, pauses, bradycardia (run), tachycardia (run)	Normal, fastest heart rate, slowest heart rate, ventricular beats, supraventricular beats, pauses, ST segment changes, prolonged QT, T-wave alternans, Heart rate turbulence, Heart Rate Variability	Normal Rhythm, Atrial fibrillation	None
Software Used	Yes	Yes	Yes	Yes
Full Disclosure				
Power Supply	Battery	Battery	Battery	Battery
Electrodes	3 integrated electrodes	3 individual electrodes	2 integrated electrodes	3 integrated electrodes
Lead Wires	Integrated into device	External	Integrated into device.	Integrated into device
Lead Vector	Lead I	Multiple	Lead I	Lead I
Sterile	No	No	No	No
Patient Contact Materials	Conventional electrodes / hydrogel	Conventional electrodes / hydrogel	Hard electrodes (metallic)	Conventional electrodes / hydrogel

None of the differences outlined in this table raise new issues of safety or effectiveness. The Indications for Use and technological characteristics of the device and its predicates are consistent with one another. Therefore, we believe the device to be Substantially Equivalent to the predicate devices.

Note: Response-Part 5 (Substantial Equivalence Discussion) contains a detailed analysis of this table.

5. Biocompatibility

No new issues of biocompatibility are raised with this device. All materials contained in the device are commonly employed in medical devices in the United States.

6. Summary of Performance Testing

The device was evaluated for safety and performance to accepted standards in a laboratory environment and detailed documentation has been provided.

Performance Documentation	**Status**
Level of Concern Determination (Moderate)	Provided
Development Plans	Provided
Device Description	Provided
System Requirement Specifications	Provided
Risk Management / Safety	Provided
Hazard Analysis Report	Provided
Component Requirement Specifications	Provided
Software/Hardware Design Descriptions	Provided
Traceability Matrix	Provided
Verification and Validation Protocols and Reports	Provided
Unresolved Anomalies (Bugs or Defects)	Provided